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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,122	LAUS ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/7/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,10,12 and 21-30* is/are pending in the application.

4a) Of the above claim(s) *21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4, 10, 12 and 21-30 are all the pending claims in this application.

2. Claim 1 was amended in the Response of 7/7/08.

3. Claims 21-30 are withdrawn from examination.

4. Claims 1, 4, 10 and 12 are all the pending claims under examination.

5. This action is FINAL.

Amendments to the Specification

6. In the Office Action of 4/20/07, the Examiner observed an apparent discrepancy between the description for the PAP/GM-CS fusion protein in the specification (513 amino acids) and for SEQ ID NO:5 (PAP/GM-CS fusion protein) of the Sequence Listing (144 amino acids). Applicants were specifically requested to address this issue in the Office Actions of 4/20/07 and 1/4/08.

Applicants have finally addressed this matter in the Response of 7/7/08 by acknowledging the error, amending the specification at p. 17, line 22 to correct the error, referencing Example 1 in the specification for PAP-linker-GM-CSF of SEQ ID NO:5 and incorporating USPN 5,976,546, 6,080,409 and 6,210,662 by reference for their disclosure of the PAP/GM-CSF protein conjugate.

Rejections Maintained

Claims - 35 USC §112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

7. The rejection of Claims 1, 4, 10 and 12 under 35 U.S.C. 112, first paragraph, as not being enabled for making or using a immunotherapeutic composition comprising a fusion protein "consisting essentially of" huPAP and huGM-CSF of SEQ ID NOS: 1 and 3, respectively, is maintained for all of the reasons set forth in the Office Actions of 4/20/07 and 1/4/08.

For purposes of clarification, the original rejection focused on the unpredictability of using APCs much less APCs stimulated with a fusion protein *ex vivo* on any subject where the fusion protein is "consisting essentially of" huPAP (SEQ ID NO:1) and huGM-CSF (SEQ ID NO:3). The basis of this rejection in the Office Action of 4/20/07 was because:

> "…the introduction of "consisting essentially of" language does not specifically exclude other elements within the composition or other elements occurring within the structure of the fusion protein, which materially effect the basic and novel characteristics of the invention , i.e., the APC and the fusion protein. In other words, the language does not exclude from the fusion protein the presence of sequences other than those coding for huPAP and huGM-CSF, and which can otherwise affect the properties of the fusion protein. Additionally, other elements of PAP and GM-CSF which can impart or effect the structural or functional properties of the molecules themselves can include, for example, a) bioeffecting regions in the full length sequence for the huPAP and/or huGM/CSF proteins, i.e., N-terminal leader sequence or transmembrane domain, other than intended APC immunostimulatory domains, and/or b) a linker peptide in the fusion protein itself.
>
> For example, the specification specifically teaches at p. 17, line 22- p. 18, line 6, a PAP/GM-CSF fusion protein of SEQ ID NO:5 as occurring between a 386 amino acid portion of PAP at the N-terminus and a 127 amino acid portion of GM-CSF at the C-terminus, with a two amino acid peptide linker having the sequence gly-ser occurring between the N- and C-terminal moieties. Notably, SEQ ID NO:5 is only 144 amino acids in length in the original and revised Sequence Listings. Applicants are requested to address this discrepancy between the specification and SEQ ID NO:5 of the Sequence Listing. Further, the specification teaches PAP/GM-CSF fusion proteins comprising sequence variations within the amino acid sequence of the PAP and GM/CSF moieties. All of the working examples

in the specification disclose the PAP/GM-CSF fusion (PA20224) indicated as comprising SEQ ID NO:5 (see Example 1).

Linker peptides discussed more specifically on pp. 18-19, are taught as being optional (see line 26), and that the linkers "are not required when the first and second polypeptides have non-essential N-terminal amino acid regions that can be used to separate the functional domains and prevent steric interference." From this disclosure, it is not even clear whether a peptide linker would be required for the instant claimed fusion protein having the full length huPAP of SEQ ID NO:1 and the full length huGM-CSF having SEQ ID NO:3.

Thus based on the foregoing analysis, the Examiner submits that the claimed immunostimulatory composition is not enabled because the claims encompass other elements that potentially materially effect the basic and novel characteristics of the composition. (see *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, (Fed. Cir. 1997) "For an inserted cDNA having a DNA sequence coding for human [PI], the word "having" still permitted inclusion of other moieties. The claims were again rejected based upon the same references and in a later requirement that the word "having" be changed to "consisting essentially of", the examiner allowed the claims, noting that the "consisting essentially of" language "excludes from the cDNA the presence of sequences other than those coding for PI.")",

and as set forth in the Office Action of 1/4/08:

"A. Applicants allege on p. 7 of the Response of 10/22/07 that in amending Claim 1 to recite "consisting essentially of" language "preceding the phrase reciting the characteristics of the fusion protein" and in having deleted the term ""having" in relation to the specific portions of the fusion protein", the immunotherapeutic composition is enabled.

Despite the amendment of Claim 1 to introduce the "consisting essentially of" language in the context of the fusion protein itself rather than the composition as a whole, the claimed composition is not any more enabled than previously recited.

The limitation does not exclude other elements from occurring within the structure of the fusion protein, which materially effect the basic and novel characteristics of the invention, i.e., the fusion protein. In other words, the language does not exclude from the fusion protein the presence of sequences other than those coding for huPAP and huGM-CSF of SEQ ID NOS: 1 and 3, respectively, and which can otherwise affect the properties of the fusion protein. Additionally, other elements of the fusion protein which may impact or effect the structural or functional properties of the molecule itself can include, *for example*, a signal peptide, a linker peptide, etc. Further, the specification teaches examples of peptide linkers (p. 18, line 34- p. 19, line 6) selected for their ability to adopt a secondary structure that could interact with functional epitopes on the first and second polypeptides or the lack of hydrophobic or charged residues that might react with the polypeptide functional epitopes. Thus, the instant claim scope in no way excludes the existence of other elements such as a peptide linker, which as taught by the specification, could in fact be selected to interact with the the huPAP and/or huGM-CSF portions of the fusion protein, and thereby materially effect the properties of the protein much less the composition.

The Examiner resubmits that the claimed immunostimulatory composition is not enabled because the claims encompass other elements within the fusion protein that may potentially materially effect the basic and novel characteristics of the composition."

Applicants' allegations on p. 7 of the Response of 7/7/08 have been considered and are not found persuasive. Applicants allege the courts have interpreted the claim language "consisting essentially of" to signal a partially open claim which is open to unlisted elements that do not materially affect the basic and novel properties of the invention (citing *PPG Industries v. Guardian Industries; Atlas Powder*).

Reply to Arguments

MPEP 2111.03 states in part:

"The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention",

but

"…absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG ***could have*** defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.")." *[Examiner's italics]*

Here as in *PPG*, the instant specification does not provide a definition for the meaning of the transitional language so the ordinary artisan could not discern what structural elements would or would not materially effect the basic and novel characteristics of the hPAP-hGM-CSF fusion protein formulated into an immunotherapeutic composition.

In *Atlas Powder*, the court interpreted the transitional language broadly, where it stated:

"Egly, which Du Pont referred to at oral argument as the "closest prior art," describes an emulsion of ammonium nitrate, water, fuel oil, and water-in-oil

> emulsifying agent. Though Egly teaches the presence of solid ammonium nitrate prills as an essential ingredient, Du Pont argues that the '978 claims, because of the phrase "consisting essentially of," does not exclude the presence of those prills. See, e.g., In re *Herz,* 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976); In re *Janakirama-Rao,* 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). Du Pont is correct."

Thus to the extent the claims encompass other elements in the composition, one skilled in the art would not have been enabled to practice using the instant claimed immunotherapeutic composition in vivo in any subject much less "a single patient diagnosed with prostate cancer having moderate- to well-differentiated cancer grade and Gleason score of 7 or less" absent further detailed experimentation.

Claims - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The rejection of Claims 1, 4, 10 and 12 under 35 U.S.C. 102(b) as being anticipated by Small et al. (J. Clin. Oncol. 18:3894-3903 (2000); hereinafter referred to as "Small"; cited in the PTO 892 form of 7/18/06) as evidenced by Ahmed et al. (J. Pak. Med. Assoc. 52:54-56 (2002); cited in the PTO 892 form of 4/20/07) is maintained.

For purposes of review, the rejection was set forth in the previous Office Action as follows:

"Applicants allege on pp. 7-10 of the Response of 10/22/07 "each preparation of dendritic cells in Small does not necessarily or inevitably result in an immunotherapeutic composition of antigen presenting cells of the instant claims because there is nothing to show that *all patients* in Small had prostate cancer having a moderately to well differentiate cancer grade and a Gleason score of 7 or less." "The mere fact that some patients may have had a prostate cancer with a Gleason score of 7 or less is not sufficient to establish inherency as evidenced by Ahmed since Ahmed "does not address the nature (i.e., Gleason score) of the prostate cancers treated in Small.

Initially, the Examiner points out that none of the instant claims are specifically limited to the composition comprising APC's from a prostate cancer patient with *only* moderate to well differentiated cancer grade and *only* a Gleason score of 7 or less. The claims necessarily encompass APC's from patients of a mixed grade and mixed Gleason score and some of which based on Small as evidenced by Ahmed could comprise the recited elements of the APC's.

Further, it is not necessary that Ahmed specifically address the exact nature of the prostate cancers treated in Small because Ahmed is cited for showing that one of skill in the art would recognize a patient having a "moderately differentiated" prostate tumors would also be associated with having a Gleason score of 5, 6 or 7 (or 7 or less) (see MPEP 2131.01).

Finally, in amending claim 1 to recite that the fusion protein consists essentially of huPAP (SEQ ID NO:1) and huGM-CSF (SEQ ID NO:3), the fusion protein now has the full length PAP and full length GM-CSF proteins of the Provenge protein of Small. The claimed fusion protein appears to be the same as the prior art Provenge molecule, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

A) Applicants' allegations on p. 9 and the 1.132 Declaration of Dr. Sims have been considered but are not found to be persuasive. Applicants have focused on the single statement from the previous Office Action that "the claims encompass patients with cancers having a "mixed grade and mixed Gleason score." The Declaration of Dr. Simms provides a detailed definition for interpreting a "Gleason score" for a patient; that a given patient would not have a "mixed" final Gleason score.

Response to Arguments

The Declaration under 37 CFR 1.132 filed 7/7/08 is insufficient to overcome the rejection of claim 1, 4, 10 and 12 based upon Small as set forth in the last Office action because Applicants have taken the single statement out of context and created an

irrelevant argument to the original rejection. It is readily apparent that Small teaches a clinical study comprising a “mixed” patient population, in other words, where each of the patients would not necessarily have had the same or similar Gleason scores from amongst the population. Small teaches:

“In the phase I component, all 12 patients had metastatic disease, and the median PSA was 209 ng/ml”…”By contrast, the patients in the phase II portion had less extensive disease. None of these patients had metastases identified by bone scan or computed tomography. An increasing PSA was the only evidence of disease progression, and the median PSA level was much lower (14.5 ng/ml; range, 3.4 to 216 ng/ml)" (p. 3896, Col. 2, ¶3-4).

Small teaches different patient populations but does not in any way teach or suggest that a given patient would have a “mixed” Gleason score. It is not clear how applicants have come to this conclusion or why any effort was dedicated to this in the prosecution proceeding.

B) Applicants’ allegations with respect to Smith as evidenced by Ahmed on pp. 9-11 of the Response of 7/7/08 have been considered but are not found persuasive. Applicants allege Small is silent with respect to the Gleason score but due to the nature of the clinical trial patients being androgen-refractory and metastatic some patients would be expected to have a Gleason score greater than 7; the patient pools of Small represent a different cross section than presently claimed; Ahmed does not disclose the Gleason score of any patient in the androgen-refractory patient pool of Small; the

biopsies of Ahmed were moderate to poorly differentiated and are not strictly identical to the presently claimed patient diagnosed with prostate cancer having a moderate to well-differentiated cancer grade and a Gleason score of 7 or less."

Response to Arguments

Applicants appear to have wholly ignored the disclosure in Small for the 19 patients enrolled in the phase II trials who exhibited a poorly to moderately differentiated prostate cancer. It is presumed that this patient population of Smith would be overlapping with the instant claimed patient population who are a) moderate to well-differentiated in their prostate cancer grade and b) have a Gleason score of 7 or less. Ahmed is an extra reference or evidence under MPEP 2131.01 (III) used to show an inherent characteristic of the thing taught by the Smtih, namely the expected Gleason score of 7 or less for a prostate cancer patient having a moderate cancer grade. MPEP 2131.01 (III), states in part:

> "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that anticipation' requires that every element of the claims appear in a single reference accommodates

> situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation."

Ahmed teaches a universal fact, namely, that one of ordinary skill in the art had already known and therefore would expect a moderate prostate cancer grade to fall within the range of a Gleason score of 7 or less.

C) Applicants allegations on p. 10 of the Response of 7/7/08 have been considered but are not found persuasive. Applicants allege: "The Small…studies describe a different cross-section of patients, a subset which may overlap with, but is distinct from the scope of the present claims. The fact that the patient may overlap with the presently claimed patient population by encompassing patients with moderately-differentiated cancer is insufficient to be anticipatory, as the Small (and Burch) references fail to disclose with sufficient specificity patients having any particular Gleason scores, much less those having a Gleason score of 7 or less" where MPEP 2131.02 is excerpted in the Response bridging pp. 11-12.

Response to Arguments

Applicants admission of record that there is an indicia of overlapping subject matter between the patient populations of Small, provides more than sufficient evidence for a prima facie case of anticipation vis-à-vis the inherent characteristics of Small's patient population reading on the instant claims as evidenced by Ahmed.

For all of the foregoing reasons, the rejection is maintained.

9. The rejection of Claims 1, 4, 10 and 12 under 35 U.S.C. 102(b) as being anticipated by Burch et al. (Clin. Cancer Research 6:2175-2182 (June 2000); hereinafter referred to as "Burch"; cited in the PTO 892 form of 7/18/06) as evidenced by Ahmed et al. (J. Pak. Med. Assoc. 52:54-56 (2002); cited in the PTO 892 form of 4/20/07) is maintained.

Applicants failed to respond outright to this rejection in the previous Office Action. Now Applicants have collectively grouped their response to the Burch reference using the same arguments against Small on pp. 8-11 of the Response of 7/708.

Response to Arguments

For purposes of brevity, the examiner incorporates the rebuttal arguments presented above under section 8 as they apply to Burch.

Claims - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The rejection of Claims 1, 4, 10 and 12 under 35 U.S.C. 103(a) as being unpatenable over Laus et al. (USPN 6,210,662, published April 3, 2001, filed June 24, 1999; cited in the PTO 892 form of 7/18/06) in view of Small et al. (J. Clin. Oncol. 18:3894-3903 (December 2000); cited in the PTO 892 form of 7/18/06) as evidenced by Ahmed et al. (J. Pak. Med. Assoc. 52:54-56 (2002); cited in the PTO 892 form of 4/20/07) is maintained.

For purposes of review, the rejection was set forth in the Office Action of 1/4/08 as follows:

"Applicants allege on pp. 11-14 of the Response of 10/22/07 Laus is a general description for use of protein complexes to stimulate APCs and the present claims are distinguishable in requiring APCs from a particular type of patient, i.e., moderate to well differentiated grade of prostate cancer and a Gleason score of 7 or less. Then Applicants make contradictory statements within ¶2 on p. 13 of the Response stating in one instance that Small does not provide motivation to select any given cancer population because the patients in Small's clinical trials had "various stages of prostate cancer" then further on they state that "Small is directed to treatment of advanced prostate cancer." Applicants further allege that Ahmed is irrelevant because it does not specifically address the types of patients in Small.

Laus explicitly teaches PAP-GM-CSF fusion polypeptides (having a gly-ser peptide linker) and exposing APCs ex vivo to the polypeptides to induce T-cytotoxic responses against for example prostate cancer. Laus cannot be any more explicit in its disclosure in using immunotherapeutic compositions comprising APCs from prostate cancer patients which are stimulated ex vivo with PAP-GM-CSF fusion proteins. The comments of Small as evidenced by Ahmed are discussed above. Despite Applicants own uncertainty regarding the teachings of Small, it is more than apparent that one skilled in the art based on the combination of references could have drawn a convincing line of reasoning based on the established scientific principles of the references that some advantage or expected beneficial result would have been produced by their combination (MPEP 2144)."

Applicants' allegations on pp. 12-13 of the Response of 7/7/08 have been considered but are not found persuasive. Applicants allege the references alone and in combination fail to teach or suggest the specific subset of prostate cancer patients with moderate to well differentiated prostate cancer having a Gleason score of 7 or less from which APCs are obtained and stimulated for inclusion in the immunotherapeutic composition as claimed; Applicants found unexpected and surprising properties of the presently claimed composition, namely, significantly enhanced response to the composition in the specific claimed population compared to patients with a Gleason score of 8 or greater.

Response to Arguments

The examiner's comments under section 8 above for Small as evidenced by Ahmed are incorporated for brevity, and further where Laus as the primary reference made the general disclosure for the instant composition (see claims 1-3) well prior to the instant filing date, the ordinary artisan would have found more than sufficient motivation to have identified stratified patient populations who were better responders compared to refractory or non-responders. In fact, the object of Small's clinical trial studies is precisely to compare different prostate cancer patient populations for the instant claimed formulation. For example, Small teaches: "The median time to disease progression for the phase I patients was 12 weeks, and the median time to progression for the phase II patients was 29 weeks. Seven of the 19 phase II patients had not progressed by the end of the planned 1-year follow-up period" (p. 3899, Col. 1, ¶2). Clearly, these data demonstrate that the patient population in the phase II trial had a

different and enhanced response to the treatment compared to the patients in the phase I trial. Thus the combined references taught the patient population of the instant claims using the very same immunotherapeutic composition of the instant claims.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the response of the claimed population is significantly enhanced to the composition compared to patient population with a Gleason score of 8 or greater) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The rejection is maintained.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643